

IN THE SPECIFICATION

Please **add** the following paragraphs on page 1, line 5, after the title:

CROSS REFERENCE TO RELATED APPLICATIONS

This application claims priority under 35 U.S.C. § 119(e) of U.S. Provisional Application No. 60/125,818 filed March 23, 1999, the disclosure of which is incorporated herein by reference in its entirety.

INCORPORATION OF SEQUENCE LISTING

A copy of the Sequence Listing in computer readable form containing the file named pa_00268.rpt, which is 27,708,052 bytes in size (measured in MS-DOS) and created on January 8, 2003, is herein incorporated by reference.

Please **amend** the specification by replacing the paragraph on page 5, lines 16-25, with the following amended paragraph:

Similarity analysis includes database search and alignment. Examples of public databases include the DNA Database of Japan (DDBJ) (~~<http://www.ddbj.nig.ac.jp/>~~) ([www-ddbj.nig.ac.jp/](http://www.ddbj.nig.ac.jp/)); Genbank (~~<http://www.ncbi.nlm.nih.gov/web/Genbank/Index.html>~~) ([www-ncbi.nlm.nih.gov/web/Genbank/Index.html](http://www.ncbi.nlm.nih.gov/web/Genbank/Index.html)); and the European Molecular Biology Laboratory Nucleic Acid Sequence Database (EMBL) (~~http://www.ebi.ac.uk/ebi_docs/embl_db.html~~) ([www-ebi.ac.uk/ebi_docs/embl_db.html](http://www.ebi.ac.uk/ebi_docs/embl_db.html)). A number of different search algorithms have been developed, one example of which are the suite of programs referred to as BLAST programs. There are five implementations of BLAST, three designated for nucleotide sequences queries (BLASTN, BLASTX and TBLASTX) and two designed for protein sequence queries (BLASTP and TBLASTN) (Coulson, *Trends in Biotechnology*, 12: 76-80 (1994); Birren *et al.*, *Genome Analysis*, 1: 543-559 (1997)).

Please **amend** the specification by replacing the paragraph from page 27, line 23 to page 28, line 3 with the following amended paragraph:

A PCR probe is a nucleic acid molecule capable of initiating a polymerase activity while in a double-stranded structure with another nucleic acid. Various methods for determining the structure of PCR probes and PCR techniques exist in the art. Computer generated searches using programs such as Primer3 ~~www-genome.wi.mit.edu/cgi-bin/primer/primer3.cgi~~ (available on the World Wide Web at www-genome.wi.mit.edu/cgi-bin/primer/primer3.cgi), STSPipeline ~~www-genome.wi.mit.edu/cgi-bin/www-STS_Pipeline~~ (available on the World Wide Web at www-genome.wi.mit.edu/cgi-bin/www-STS_Pipeline) or GeneUp (Pesole *et al.*, *BioTechniques* 25:112-123 (1998) the entirety of which is herein incorporated by reference), for example, can be used to identify potential PCR primers.

IN THE CLAIMS

Please **cancel** non-elected claims 2-7 without prejudice to or disclaimer of the subject matter contained therein. Please **amend** claim 1. Please **add** new claims 8-13.

1. (Currently Amended) A substantially purified nucleic acid molecule that encodes a soybean protein or fragment thereof comprising a nucleic acid sequence ~~selected from the group consisting of SEQ ID NO: 1 through SEQ ID NO: 27422~~ of SEQ ID NO: 5981.

2.-7. (Cancelled)

8. (New) A substantially purified nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 5981 or complement thereof.

9. (New) The substantially purified nucleic acid molecule according to claim 8, wherein said nucleic acid molecule consists of a nucleic acid sequence of SEQ ID NO: 5981 or complement thereof.

10. (New) A substantially purified nucleic acid molecule comprising a nucleic acid sequence having between 100% and 90% sequence identity with a nucleic acid sequence of SEQ ID NO: 5981 or complement thereof.

11. (New) The substantially purified nucleic acid molecule of claim 10, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 95% sequence identity with a nucleic acid sequence of SEQ ID NO: 5981 or complement thereof.

12. (New) The substantially purified nucleic acid molecule of claim 11, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 98% sequence identity a the nucleic acid sequence of SEQ ID NO: 5981 or complement thereof.

13. (New) The substantially purified nucleic acid molecule of claim 12, wherein said nucleic acid molecule comprises a nucleic acid sequence having between 100% and 99% sequence identity with a nucleic acid sequence of SEQ ID NO: 5981 or complement thereof.

Remarks

I. Support for the Amendments

Non-elected claims 2-7 have been canceled without prejudice to or disclaimer of the underlying subject matter. Claim 1 has been amended to recite the elected SEQ ID NO. New claims 8-13 have been added. Support for the foregoing claim amendments and new claims may be found throughout the specification, in the sequence listing, and in the original claims, for example from page 9, line 23, through page 10, line 11, and page 19, line 17, through page 20, line 10. Upon entry of the foregoing amendments, claims 1 and 8-13 are pending in the application.

The specification has been amended to claim priority to provisional application number 60/125,818, as indicated in the declaration. The specification has also been amended to explicitly reference the sequence listing in computer readable form in the present application, and to remove embedded hyperlinks and underlining from all website addresses. No new matter enters by way of these amendments.

II. The Restriction Requirement

Applicants acknowledge the finality of the restriction requirement but maintain their traversal. To facilitate prosecution, however, Applicants have removed the non-elected claims from the application.

Applicants also acknowledge the finality of the election requirement to a single nucleotide sequence, but maintain their traversal. Applicants respectfully disagree that the polynucleotide sequences of the instant application would be considered of the complexity that merits restriction to a single sequence in contradiction to the expressed USPTO policy of examining ten sequences, as set forth in the Manual of Patent Examining Procedure. (*See*, M.P.E.P., 8th ed., August 2001, Section 803.04, page 800-10). However, in order to facilitate prosecution Applicants have removed non-elected sequences from the claims.

III. Information Disclosure Statement

Applicants acknowledge and thank the Examiner for attaching an initialed copy of the FORM PTO-1449 (Information Disclosure Statement), filed on March 22, 2000, with this action.

IV. Specification

The “http://,” underlining, and embedded hyperlinks have been removed from website addresses on pages 5 and 26 of the specification. The specification has also been objected to at page 7 for purportedly containing embedded hyperlink and/or other form of browser-executable code. Applicants respectfully disagree.

The purpose of the requirement that hyperlinks or other forms of browser executable code be removed from the specification is so that on the United States Patent and Trademark Office website, one cannot click on the hyperlink and be transported to another, potentially commercial, website. This requirement does not exclude the listing of a website that is not present as a hyperlink.

Although it is possible to click on this purported “hyperlink” in a Microsoft Word document and be transported to the corresponding website, or even to copy and paste this purported “hyperlink” into the address location in Microsoft Explorer, this purported “hyperlink” would not be usable when placed on the United States Patent and Trademark Office website. For example, a search of the United States Patent and Trademark Office patent database using “www.ncbi.nlm.nih.gov” identified 63 patents citing this website, including USP 6,552,250. In the ‘250 patent, the citation of this website using this exact format does not result in a useable hyperlink. Furthermore, the format used by Applicants excludes the “www.” portion of this web address. Therefore, the citation of a website in this format does not offend United States Patent and Trademark Office policy, and should be allowed in an application.

The website addresses on page 7 of the disclosure, described by the Examiner as containing embedded hyperlink and /or other forms of browser executable code, do not

contain such browser-executable code as specified in M.P.E.P. § 608.01. According to M.P.E.P. § 608.01, “examples of a hyperlink or browser-executable code are a URL placed between these symbols ‘<>’ and ‘http://’ followed by a URL address.”

Applicants’ disclosure, as amended, contains no browser-executable code in the absence of embedded hyperlinks and/or other forms of browser-executable code. *See*, M.P.E.P. § 608.01. Accordingly, in light of these remarks, Applicants respectfully request that the Examiner withdraw the objection.

V. Rejection of Claim 1 Under 35 U.S.C. § 112, First Paragraph, Written Description

The Examiner has rejected claim 1 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Office Action at pages 3-5. Applicants respectfully disagree.

Although the Examiner acknowledges that the specification discloses SEQ ID NO: 5981, claim 1 allegedly fails to meet the written description requirement because the “specification provides insufficient written description to support the genus encompassed by the claim.” Office Action at page 3. Applicants respectfully disagree with this contention.

An adequate written description of a genus of nucleic acids, as recited in claim 1 may be achieved by either “a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus.” *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

The purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479,

45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, Applicants need not “describe,” in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims “may be broader than the specific embodiment disclosed in a specification.” *Ralston Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985), *quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981). Thus, in order for Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules (*e.g.*, an open reading frame) be disclosed. *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996) (if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing even if every nuance of the claims is not explicitly described in the specification).

The Examiner further contends that “the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins”. Office Action at page 4. According to the Examiner, proper written description support for a claim directed to a nucleic acid sequence requires nothing less than the actual disclosure of every sequence encompassed by that claim. In support of this proposition, the Examiner relies on *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997). Applicants respectfully disagree. In *Eli Lilly* the court found that claims to a vertebrate cDNA coding insulin were inadequately described. However, the present case is clearly different. Specifically, the present claims “distinguish the claimed genus from others” and define “structural features commonly possessed by members of the genus that distinguishes them from others,” unlike the claims at issue in *Eli Lilly*. *Id.* at 1568-69 (“a cDNA is not defined or described by the

mere name 'cDNA'...but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA.”).

In particular, Applicants have provided a detailed chemical structure, *i.e.*, the nucleic acid sequence of SEQ ID NO: 5981. Moreover, nucleic acid molecules falling within the scope of claim 1 are readily identifiable – they comprise a nucleic acid molecule having the nucleic acid sequence of SEQ ID NO: 5981. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed through the present specification. Thus, there is no deficiency in the written description support for claim 1. Therefore, claim 1 satisfies the written description requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

VI. Rejection of Claim 1 under 35 U.S.C. § 101: Utility

The Examiner has rejected claim 1 under 35 U.S.C. § 101, for allegedly lacking a patentable utility. Office Action at pages 6-7. Applicants respectfully disagree.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including nucleic acid compounds “as probes for assisting in the isolation of full-length cDNA’s or genes which would be used to make protein and optionally further usage to make the corresponding antibodies, gene mapping, isolation of homologous sequences, detection of gene expression such as in Northern blot analysis, molecular weight markers, chromosomal makers, and for numerous other generic genetic engineering usages [and]...protein...for detection of expression, antibody production, Western blots, or animal feed, or human consumption etc.” Office Action pages 6-7. However, the Examiner contends that none of these utilities are “specific and substantial.” Applicants respectfully disagree with this assertion.

It is well-established that “when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown.” *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 298 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention. In addition to the utilities described by the Examiner (quoted above), the claimed nucleic acid molecules are useful for isolating a variety of agronomically significant genes, acquiring molecular markers, promoters, cis-regulatory elements, etc. *See, e.g., page 31* under “Uses of the Agents of the Invention.”

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell or organism. Significantly, the utility of the microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize other nucleic acid molecules within a sample, cell or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather the Examiner attempts to undermine the existing utilities by stating that they are not specific and are “generally applicable to any nucleic acid and/or protein” and further asserts that the disclosure utilities are “non-specific uses that are applicable to nucleic acid(s) and/or proteins in general and not particular or specific to the nucleic acid(s) and/or protein(s) being claimed..” Office Action at pages 6-7. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) (“An invention need not be the best or the only way to accomplish a certain result...”).

Moreover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires reading “into the patent laws limitations and conditions which the legislature has not expressed,” a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 306 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 163 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

As noted above, the claimed nucleic acid molecules have many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and locate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a *unique* subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit a ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. § 101.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by specific and substantial utilities disclosed in the specification. Consequently, the rejection of claim 1 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

VII. Rejection of Claim 1, Under 35 U.S.C. § 112, First Paragraph, Enablement

The Examiner has rejected claim 1 as not being enabled by the specification, because the claimed invention allegedly lacks utility. Office Action pages 7-8. Applicants respectfully disagree and assert that the rejection has been overcome by the

foregoing arguments regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Reconsideration and withdrawal are respectfully requested.

VIII. The Rejection of Claim 1 under 35 U.S.C. § 102

The Examiner has rejected claim 1 under 35 U.S.C. § 102(b) as anticipated by Biolabs, New England, Catalogue (Page 48, nucleic acid sequences of Column 1, Product #169S and #122S, 1996). The Examiner's position is based on the allegation that Product #169S and #122S teaches "a substantially purified nucleic acid molecule that encodes a fragment of soybean protein, comprising a nucleic acid sequence of SEQ ID NO: 5981." Office Action at page 7. Applicants respectfully disagree.

"It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q. 619 (Fed. Cir. 1985).

In the present application, pending claim 1, as amended, is directed to a substantially purified nucleic acid molecule that encodes a soybean protein or fragment thereof comprising a nucleic acid sequence of SEQ ID NO: 5981. The Examiner has applied an untenable interpretation of claim 1 to cover small fragments of the specifically claimed nucleic acid molecule, *i.e.*, molecules as short as one codon, and thus concludes that the claim is anticipated by the cited reference. Office Action at page 8. A grammatically consistent interpretation of the claim at issue would relate the phrase "or fragment thereof" in the preamble back to the phrase "soybean protein" directly preceding it. Further, because the phrase "or fragment thereof" appears before the transition phrase "comprising," it is clear that it does not refer to a fragment of SEQ ID NO: 5981.

As such, pending claim 1 is directed to a nucleic acid molecule which encodes a soybean protein or fragment thereof, *i.e.*, a fragment of a soybean protein, comprising the nucleic acid sequence of SEQ ID NO: 5981. Whatever else the Biolabs Catalogue teaches, it does not disclose SEQ ID NO: 5981. Absent a teaching of each and every element of the claim, including the nucleotide sequence of SEQ ID NO: 5981, the reference cited by the Examiner does not anticipate claim 1.

In view of the above, Applicants contend the rejection under 35 U.S.C. § 102(b) is improper. Reconsideration and withdrawal of this rejection is respectfully requested.

Conclusion

In view of the above, the presently pending claims are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and pass the application to issue. The Examiner is encouraged to contact the undersigned with respect to any unresolved issues remaining in this application.

Respectfully submitted,

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Date: August 19, 2003

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